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| 09/801,443 | 03/07/2001 | Suneel K. Gupta | ARC 2863 N1 | 7756 |

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EXAMINER

TRAN, SUSAN T

ART UNIT PAPER NUMBER

1615

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,443

Applicant(s)

GUPTA ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>05/23/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination filed 07/14/05, Information Disclosure Statement filed 05/23/05, and Amendment filed 03/03/05.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/14/05 has been entered.

Response to Amendment

The amendment filed 07/14/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "determining an oxybutynin plasma concentration in the patient in said fasted state", "determining an oxybutynin plasma concentration in the patient in said fed state", and "comparing an oxybutynin plasma concentration observed in said fed state with an oxybutynin plasma concentration observed in a fasted state" steps in the claimed process.

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Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering a sustained release dosage form to a patient, does not reasonably provide enablement for administering any dosage form as claimed in claims 1-50. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. In order to achieve the claimed plasma concentration in the fasted or fed state, the instant specification discloses a sustained release dosage form with a specific structure (see from page 8). Accordingly, these claims fail to comply with the scope of enablement requirement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. US 5,912,268, in view of Oshlack et al. US 5,965,161.

Guittard discloses a method for administering a controlled release dosage form comprising oxybutynin, its racemate, its R-enantiomer and its S-enantiomer (see abstract, column 2, lines 31-48; and column 12, lines 40-45). Guittard also teaches administering oxybutynin for incontinence therapy, e.g., increasing the urinary bladder capacity, and diminishing the frequency of uninhibited contractions of the detrusor muscles (relaxing bladder muscles), (see column 3, lines 24-28; and column 4, lines 13-21).

Guittard does not expressly teach the dosage form, which would exhibit the same plasma concentration in fed state as well as fasted state.

Oshlack teaches a sustained release unit dosage form comprising anti-spasmodic active agent suitable for once-a-day product without a food effect (see abstract; and column 13, lines 8-10). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release dosage form of Guittard using the sustained release dosage form in view of the teaching of Oshlack to obtain the

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claimed invention, because Oshlack teaches a sustained release dosage form that release the drug in such a rate that plasma concentrations are maintained within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 5, lines 1-4), because Guittard teaches a dosage form that reduces and/or eliminates the unwanted influences of the gastrointestinal environment of the use and still provides controlled release of oxybutynin over time, and because Guittard teaches a dosage form that provides release of oxybutynin at plasma concentrations within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 13, lines 5-10). The expected results would be a sustained release dosage form of oxybutynin that is free of food effect.

Claims 15-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al. US 5,912,268, in view of Morella et al. US 5,378,474.

Guittard does not expressly teach the dosage form, which would exhibit the same plasma concentration in fed state as well as fasted state.

Morella teaches a sustained release dosage form comprising smooth muscle relaxant agent, such as oxybutynin hydrochloride (see abstract, and column 5, lines 34-36). Morella further teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65). The dosage form further shows no evidence of dose dumping, and the relative bioavailability of the active ingredient is not compromised by food so that compliance will improve as the product may be taken without regard to meals (column

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7, lines 35-40). Thus, it would have been obvious to one of ordinary skill in the art to modify the controlled release dosage form of Guittard using the sustained release dosage form in view of the teaching of Morella to obtain the claimed invention, because Morella teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65), because Morella teaches the sustained release dosage form can be taken without regard to meals (column 7, lines 35-40), because Guittard teaches a dosage form that reduces and/or eliminates the unwanted influences of the gastrointestinal environment of the use and still provides controlled release of oxybutynin over time, and because Guittard teaches a dosage form that provides release of oxybutynin at plasma concentrations within the therapeutic range but below toxic levels over a period of time of up to about 24 hours or longer (column 13, lines 5-10). The expected results would be a sustained release dosage form of oxybutynin that is free of food effect.

Claims 15, 16, 21-25, 39-43 and 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morella et al. US 5,378,474, in view of Lukkari et al. (Eur. J. Pharmacology).

Morella teaches a sustained release dosage form comprising smooth muscle relaxant agent, such as oxybutynin hydrochloride (see abstract, and column 5, lines 34-36). Morella further teaches the dosage form exhibits less fluctuation in plasma concentrations in active ingredient at steady state over a 24 hours period (column 6, lines 63-65). The dosage form further shows no evidence of dose dumping, and the

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relative bioavailability of the active ingredient is not compromised by food so that compliance will improve as the product may be taken without regard to meals (column 7, lines 35-40).

Morella teaches oxybutynin among a number of other drugs.

Lukkari specifically teaches the effect of food on the bioavailability of oxybutynin from a controlled release tablet (page 221). Lukkari concludes that the effect of food is of limited clinical significance, and the pharmacodynamic effects are not to be altered by eating (page 223). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the sustained release dosage form of Morella to obtain a sustained release dosage form of oxybutynin in view of the teaching of Lukkari, because the references teach the desirability to achieve a sustained release dosage form containing oxybutynin that is free of food effect.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Seth, and Sanders et al. are cited as of interest for the teachings of composition that is free of food effect.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal line extending to the right.

S. Tran
Patent Examiner
AU 1615